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AN ARD-CHÚIRT
THE HIGH COURT

JUDICIAL REVIEW

2022 No 1085 JR

**MONDAY THE 6TH DAY OF NOVEMBER 2023
BEFORE MR JUSTICE CIAN FERRITER**

BETWEEN

**PJ CARROLL & COMPANY LIMITED AND NICOVENTURES TRADING
LIMITED**

APPLICANTS

-AND-

**THE MINISTER FOR HEALTH, IRELAND AND THE ATTORNEY
GENERAL**

RESPONDENTS

**PHILIP MORRIS LIMITED, PHILIP MORRIS PRODUCTS SA and PHILIP
MORRIS MANUFACTURING & TECHNOLOGY BOLOGNA SPA
(BY ORDER OF THE COURT)**

NOTICE PARTIES

Upon Motion of Counsel for the Applicants made unto the Court this day pursuant to Notice of Motion filed on the 13th day of January 2023 seeking the following reliefs: “

1. “A declaration that Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products (the “Delegated Directive”) is invalid and,

THE HIGH COURT

accordingly, is not binding upon the Second Respondent pursuant to Articles 288 and / or 291(1) of the Treaty on the Functioning of the European Union (“TFEU”).

2. A declaration that regulations enabling the Delegated Directive to have full effect in national law in accordance with Section 2 of the European Communities Act 1972 (as amended) (the “1972 Act”) would be ultra vires the powers conferred by Section 3(1) of the 1972 Act and would be contrary to Article 15.2.1 of the Constitution (law-making power in the State).
3. A declaration that national law measures made or enacted for the purpose of complying with the Delegated Directive would breach Directive 2014/40/EU of 3 April 2014 on the the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (the “TPD”) in the absence of a valid amendment of the TPD permitting Member States to prohibit tobacco products with a characterising flavour or containing flavourings in their components, other than cigarettes and roll-your-own tobacco.
4. An order of certiorari quashing the determination of the First and / or second Named Respondent to adopt, publish and apply provisions of Irish law necessary to comply, or for the purpose of complying, with the Delegated Directive.
5. An order referring the questions set forth in Annex 1 hereto to the Court of Justice of the European Union (“CJEU”) for a preliminary ruling pursuant to Article 267 of the TFEU.
6. The costs of and incidental to these proceedings.
7. Any further or other order that this Honorable Court deems appropriate.”

THE HIGH COURT

And the matter coming on for hearing on the 11th and 12th days of July 2023 in the presence of Counsel for the Applicant and Counsel for the Respondents and Counsel for the Notice Parties

Whereupon and on reading said Notice of Motion the Order herein dated the 11th day of January 2023 giving leave to the Applicant to apply by way of judicial review the reliefs set out Statement of Grounds the Affidavit of Simon Carroll herein filed on the 13th day of December 2022 verifying the facts set out in the said Statement the Affidavit of Elly Criticou filed on the 13th day of December 2022 the exhibits referred to in said Affidavits the submissions and pleadings herein

And on hearing said Counsel

The Court was pleased to reserve its judgment

And judgment having been delivered electronically on the 15th day of September 2023 and submissions thereafter being invited and received

And in accordance with the judgment

IT IS ORDERED that in principle and subject to a formal Order of the Court an Article 267 TFEU reference will be made herein to the Court of Justice of the European Union (“CJEU”)

And the matter coming before the Court on the 9th day of October 2023 in the presence of said Counsel and the Court having directed that the parties prepare and deliver draft questions for the Court together with a draft formal Order for Reference for consideration of the Court thereafter been provided to the Court

And the matter being further adjourned to the 2nd day of November 2023 and the Court thereafter reserving its decision on the draft Agreed form of Order for Reference

THE HIGH COURT

The Court was pleased to approve the Agreed Form of Order for Reference on the 6th day of November 2023 and in accordance with the written judgment of the 15th day of September 2023

IT IS ORDERED that a reference will be made as set forth in the Order for Reference as agreed by the parties and approved by the court annexed as a

Schedule hereto to the Court of Justice of the European Union (“CJEU”) for a preliminary ruling pursuant to Article 267 of the TFEU

**ALICE WALSH
REGISTRAR
Perfected:29th November 2023**

Matheson LLP
Solicitors for the Notice Parties

A&L Goodbody LLP
Solicitors for the Applicants

Chief State Solicitor
Solicitor for the Respondents

SCHEDULE

THE HIGH COURT

2022 No. 1085 JR

BETWEEN:

PJ CARROLL & COMPANY LIMITED and NICOVENTURES TRADING LIMITED

Applicants

-and-

THE MINISTER FOR HEALTH, IRELAND and THE ATTORNEY GENERAL

Respondents

-and-

**PHILIP MORRIS LIMITED and PHILIP MORRIS PRODUCTS SA and
PHILIP MORRIS MANUFACTURING & TECHNOLOGY BOLOGNA SPA**

Notice Parties

**ORDER FOR A REFERENCE TO THE COURT OF JUSTICE OF THE
EUROPEAN UNION**

The Referring Court

This request for a preliminary reference pursuant to Article 267 of the Treaty on the Functioning of the European Union (the “**TFEU**”) is made by the High Court of Ireland (Mr. Justice Ferriter). The contact details for communications from the Court of Justice are as follows: Principal Registrar, The High Court, Four Courts, Inns Quay, Dublin 7, Ireland.

The Parties to the Irish Proceedings and their Representation

The Applicants are represented by Margaret Gray SC and Patrick Mair BL of the Bar of Ireland, instructed by A&L Goodbody LLP of 3 Dublin Landings, North Wall Quay, Dublin 1, D01 C4E0, Ireland.

The Respondents are represented by Eileen Barrington SC and Lewis Mooney BL of the Bar of Ireland, instructed by the Chief State Solicitor’s Office of Osmond House, Ship Street Little, Dublin 8, Ireland.

The Notice Parties are represented by Eoin McCullough SC and Niall Buckley BL of the Bar of Ireland, instructed by Matheson LLP of 70 Sir John Rogerson’s Quay, Dublin 2, Ireland.

The Subject Matter of the Proceedings

A ruling is required from the Court of Justice of the European Union (the “**CJEU**”) as to the validity of Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products (the “**delegated directive**”).

The dispute in the proceedings concerns the validity or otherwise of the delegated directive. The Applicants are seeking, among other reliefs, a declaration that the European Union (Manufacture, Presentation and Sale of Tobacco and Related Products) (Amendment) Regulations 2023 (the “**2023 Regulations**”) which transpose the delegated directive into Irish law are invalid.

In deciding the issues in the Proceedings, a ruling of the CJEU is necessary as the Irish Court has no jurisdiction to declare an EU act invalid.

1. Questions Referred for a Preliminary Ruling

1.1. **Question 1:** Is the delegated directive invalid on the basis that it goes beyond the powers granted by Articles 7(12) and 11(6) of Directive 2014/40/EU, in light of Article 290 TFEU, and taking into account Article 2(14), 19 and 28 of Directive 2014/40/EU?

1.2. **Question 2:** Is the delegated directive invalid on the basis that the Commission was not entitled to conclude that there was a substantial change of circumstances within the meaning of Article 7(12) and/or 11(6) and/or 2(28) of Directive 2014/40/EU?

EU law instruments at issue in the Proceedings

Tobacco Products Directive

The Proceedings relate to certain rules and exemptions from those rules provided in Directive 2014/40/EU on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products (the “**TPD**”) in respect of heated tobacco products (“**HTPs**”).

Articles 7(1) and 7(7) prohibit the placing on the market of tobacco products with a characterising flavour and/or with components containing flavouring. Article 7(12) removes this exemption for all tobacco products other than cigarettes and roll-your-own tobacco and provides the Commission with the power to adopt delegated acts in accordance with Article 27 to withdraw that exemption for a particular product category, if a substantial change of circumstances is established in a Commission report. Article 2(28) defines the term ‘*substantial change of circumstances*’ in this regard.

Certain provisions of the TPD are addressed to tobacco products for smoking while other provisions are addressed to tobacco products more generally. Article 2(5) defines “*smokeless tobacco products*” and Article 2(9) defines “*tobacco products for smoking*”.

Articles 9(2) and 10 require tobacco products for smoking to carry an information message and combined health warnings that are detailed in the TPD. Article 11(1) allows Member States to exempt tobacco products for smoking other than cigarettes and roll-your-own tobacco from these requirements. Article 11(6) provides for the possibility of this

exemption to be removed if the Commission establishes in a report that there has been a “*substantial change of circumstances*” as defined in Article 2(28).

Tobacco products are defined in Article 2(4) of the TPD. Individual categories of tobacco products are itemised in Article 2(14)(a) and each have their own definition in Article 2. Article 2(14) defines the term “novel tobacco products”, and under Article 19(4), the relevant provisions of the Directive which apply depends on whether those products are “*smokeless tobacco products*” or “*tobacco products for smoking*”.

Article 28(1) directs the Commission (with the assistance of “*scientific and technical experts*”) to submit a review report (relating to the implementation and impact of the TPD) within a specified timeframe. Article 28(2) provides that the Commission in its report must indicate, in particular, “*the elements of the Directive which should be reviewed or adapted in the light of scientific and technical developments,*” with the Commission being obliged to pay special attention to “*(b) market developments concerning novel tobacco products considering... and (c) market developments which constitute a substantial change of circumstances*”.

On 20 May 2021, the Commission submitted a report pursuant to its obligations (the “**Review Report**”) in which it adverted to the difficulty of categorising HTPs within the terms of the TPD.

Commission Implementing Decision

Articles 5(1) and 5(6) TPD provide that Member States shall require manufacturers and importers of tobacco products to submit to their competent authorities various specified information by brand name and type, including information as to the weight by ingredient in each tobacco product including “*their sales volumes per brand and type, reported in sticks or kilograms and per Member State on a yearly basis*”.

Article 5(5) provides that the Commission shall by means of implementing acts lay down the format of making available of such information. Such an implementing decision was promulgated by the Commission’s “*implementing decision establishing a format for the submission and making available of information on tobacco products*” of 25 November 2015 ((EU) 2015/2186) (the “**implementing decision**”). The implementing decision sets out (in Article 2) a format for data submission on, *inter alia*, sales volumes in accordance with a format provided for in an annex to the implementing decision. The format provides for the provision of information by product type, including product unit weight, product unit tobacco weight and “*product sales volume*”.

Delegated Directive

On 15 June 2022, the Commission published a report on the matter of a substantial change of circumstances for the purpose of Articles 7(12) and 11(6) TPD in relation to flavoured HTPs (the "**Commission Report**"). The Commission Report states that the analysis presented was based on data transmitted in accordance with Article 5(6) via the EU Common Entry Gate, and concluded that *inter alia* (i) the sales volumes of HTPs at retail level increased by a percentage higher than 10% in more than five Member States between 2018 and 2020; and (ii) the sales volumes of HTPs at retail level corresponded to 3.3% of the total sales volume of all tobacco products at Union level for the year 2020, thereby exceeding the 2.5% market share threshold in Article 2(28) of the TPD. The Commission Report also assessed whether there was a material increase in the use of HTPs by the under 25 years consumer group and found that this was not the case.

On 29 June 2022, the Commission adopted the delegated directive, which triggered a two-month scrutiny period by the European Parliament and Council (which was extended by a further two months on 18 July 2022.) No objections were raised by Council or Parliament although Bulgaria, Cyprus, Greece and Italy submitted a joint declaration formally registering their objections on the basis that it "*goes beyond the delegated power under [the TPD] and involves essential elements reserved for the European legislators*".

On 3 November 2022, the delegated directive was published in the Official Journal of the European Union and came into force on 23 November 2022.

The delegated directive made textual amendments to Article 7(12) and 11(1) TPD, withdrawing the benefit of exemptions from HTPs. The newly substituted Article 7(12) contains a definition of HTPs not previously contained in the TPD, which provides that "*depending on its characteristics*", HTPs may be a "*smokeless tobacco products*" or a "*tobacco products for smoking*". This newly defined product category is then incorporated into Article 11(1).

Relevant Provisions of National Law

The 2023 Regulations transpose the delegated directive by amending Regulation 8 of the European Union (Manufacture, Presentation and Sale of Tobacco and Related Products) Regulations 2016 to reflect the provisions of the delegated directive.

On 26 June 2023, the Minister for Health signed the 2023 Regulations into law and they were laid before the Oireachtas on 28 June 2023. The notice of the making of 2023 Regulations was published in “Iris Oifigiúil” of 30 June 2023. The 2023 Regulations will come into operation on 23 October 2023.

Factual and Procedural Background

The Applicants and the Notice Parties market or plan to market HTPs, including those with characterising flavours and/or with components containing flavouring, throughout the EU.

On 11 January 2023, the Irish High Court granted the Applicants leave to issue the Proceedings.

On 11-12 July 2023, the Proceedings were heard by the Irish High Court (Mr Justice Ferriter). On 15 September 2023, judgment was delivered deciding to request a preliminary ruling from the CJEU regarding the validity of the delegated directive.

The Principal Arguments of the Parties in the Proceedings

The Applicants’ and Notice Parties’ position is that the delegated directive is invalid and consequently, the 2023 Regulations are unlawful. They argue as follows:

Exercise of delegated powers / Article 290 TFEU

Where Articles 7(12) and 11(6) impose an obligation on the Commission to withdraw exceptions for “*a particular product category*”, the product categories in question are those specifically listed in Article 2(14)(a) TPD (i.e. those in existence at the time of enactment of the TPD and defined in the TPD). Those provisions do not empower the Commission to withdraw exemption for a “*novel tobacco product*” as defined in Article 2(14)(a). This reading is supported by the CJEU’s decision in Case C-220/17 Planta-Tabak Manufaktur (ECLI:EU:C:2019:76) which concerned the proper interpretation of the phrase “*product category*” in Article 7(14).

The Commission’s delegated powers in Articles 7(12) and 11(6) cannot be used to define and then regulate (to the point of outright prohibition) novel tobacco products that the EU legislature has never specifically considered nor made political choices in respect of.

Doing so involves legislating for a political or policy choice which is an essential element of the TPD that is reserved to the legislative act and cannot be the subject of a valid exercise of delegated power.

No power to define a new tobacco product category, and thereafter regulate it by withdrawal of an exemption, was explicitly conferred by the TPD.

Accordingly, the delegated directive is inconsistent with both limbs of the second subparagraph of Article 290(1) TFEU and goes beyond the delegated powers granted.

The overall structure of the TPD reflects that the EU legislature has set up a system in which tobacco products that were known at the time of the TPD's enactment could be subject to certain further obligations by delegated acts of the Commission. It further provided that new or little-known products should be monitored to allow the EU legislature to adopt new restrictions in the future when the nature and effects of such products have been established and appropriate legislative responses decided upon at primary level. This is reflected in the terms of the TPD with the creation of specifically defined categories of tobacco products in Article 2 and the regulation of these categories depending on which specifically defined product is in issue.

Article 28(2) TPD provides that the Commission, in its review report, must pay "*special attention*" to "*market developments concerning novel tobacco products*" and, separately, "*developments which constitute a substantial change of circumstances*", thereby, underscoring that the substantial change of circumstances analysis applies to pre-existing and not novel tobacco products under the TPD.

The Review Report signalled an acceptance by the Commission that novel tobacco products such as HTPs presented particular regulatory challenges which could only be addressed by primary legislation. Further, it would be illogical if the Commission were able to create new product categories to which it could then retrospectively apply historical data in order to establish a "substantial change of circumstances" for the purposes of Article 2(28) TPD.

The delegated directive exceeded its delegated power, and impermissibly sought to legislate for essential elements of the TPD by introducing a new "*particular product category*" that simultaneously covers both "*smokeless tobacco products*" and "*tobacco products for smoking*". The TPD clearly distinguishes between smokeless tobacco products and tobacco products for smoking, and sets very different and more onerous labelling and packaging rules for the latter. Article 19(4) TPD explicitly provides that novel tobacco products fall within one category or the other, such a product cannot fall into both.

Determination of substantial change of circumstances

The manner in which the Commission approached the question of substantial change of circumstances exceeded the Commission's delegated power under the TPD. The Commission devised and relied upon a flawed methodology in its examination of whether the last limb of Article 2(28) – the 2.5% market share threshold – had been satisfied. In doing so, the Commission exceeded the scope of the “*technical task*” concerned upon it by Articles 7(12) and 11(6) such as to invalidate the delegated directive.

The Commission improperly relied on volume of cigarettes and other tobacco products, including HTPs, on a “*per stick*” basis when it should have relied on a “*per weight*” basis in circumstances where HTPs have some 50% of the weight of tobacco which ordinary cigarettes have and where the “*per weight*” information was available to enable a more reliable “*like for like*” sales volume analysis. In adopting such a fundamentally flawed methodology, the Commission exceeded the scope of the technical task conferred on it by Articles 7(12) and 11(6).

The amount of tobacco in each of the various product categories, including HTPs, was the only correct criterion for the Commission's calculations given the TPD's focus on regulating the health effects of tobacco. The Commission's decision to use a stick-based calculation, without taking into consideration the differences in the amount of tobacco in the sticks of different products is flawed and unreliable.

Tobacco product manufacturers and distributors are obliged by virtue of the implementing decision to provide data on tobacco weight per product, meaning that the Commission had the necessary data to properly conduct a fair and valid assessment of market share by reference to the more appropriate metric of tobacco weight. If the market share of HTPs had been measured by tobacco weight and not on a stick basis, the 2.5% threshold would not have been reached, in circumstances where HTPs have some 50% of the weight of tobacco in ordinary cigarettes. The Commission exceeded its delegated powers by devising a fundamentally flawed methodology that led to a fundamentally flawed outcome with the improper result that flavoured HTPs were prohibited by the delegated directive when they should not have been.

The Respondents argue as follows:

Exercise of delegated powers / Article 290 TFEU

The TPD seeks to cast a wide and dynamic regulatory net in keeping with the objectives for which it was introduced, being to harmonise the

common market in tobacco products, to take as a base a high level of protection for health, and to be in a position to react to market developments including the introduction of novel tobacco products.

The TPD is clear in covering all “*tobacco products*” within the wide definition of that concept in Article 2 which inevitably includes both tobacco products in existence at the time of the TPD’s enactment and novel tobacco products within the wide definition in Article 2(14), i.e. tobacco products which have come into being since April 2014, such as heated tobacco products.

As there is no definition of “*other product categories*” or “*particular product categories*” in Articles 7(12) and Article 11(6), those phrases must accordingly be given their ordinary meaning, adopting a teleological interpretation of the TPD, i.e. that they include any tobacco product category, including HTPs, which comes within the broad umbrella definition of “*tobacco product*”. *Planta Tabak* was confined to the specific question of the proper interpretation of “*other product category*” in Article 7(14) TPD and does not provide support for the quite different case made in the Proceedings.

The Applicants and Notice Parties accept that HTPs are within the prohibitions in Articles 7(1) and 11(1) and the exemptions from those prohibitions in Articles 7(12) and 11(6). They then artificially and in a manner inconsistent with the objectives and wide regulatory net of the TPD, seek not to be subject to those parts of Articles 7(12) and 11(6) which mandate the Commission to disapply the exemptions once the substantial change of circumstances criteria are met. This would effectively give *carte blanche* to the unregulated introduction of flavoured novel tobacco products, such as flavoured HTPs, in a manner inconsistent with the express regulatory objectives of the TPD. Article 19(4) makes clear that the provisions of the TPD apply to novel tobacco products which must mean that Articles 7(12) and 11(6) apply to HTPs.

The exemption from prohibition of tobacco products with characterising flavours pursuant to Articles 7(12) and 11(6) is a technical task which occurs once certain objective criteria are met under Article 2(28) TPD. The policy issues and political questions on these matters are all resolved within the terms of the TPD. The impugned provisions simply set out the scope of the technical task which the Commission properly embarked upon in respect of HTPs in furtherance of the delegated powers given to it to implement the policy matters already decided upon in the provisions of the TPD, and the Commission did not amend the essential elements of the basic legislative act.

The delegated directive's explanatory memorandum made clear that the policy choices to prohibit the placing on the market of tobacco products with characterising flavours had already been made by the EU legislature in the TPD itself (as supported by Recitals 19 and 26). The delegated power clearly extends to defining a new tobacco product category for the purposes of disapplying the exemption from prohibition contained in Articles 7(12) and 11(6) as part of the policy of fulfilling the technical task of determining whether any given tobacco product is the subject of a substantial change of circumstance.

The TPD itself respects the content of, and proper limits to, Article 290 TFEU as borne out by Recitals 51 and 52 and the provisions of Articles 27 and 28. The policy on full regulation by prohibition of flavoured tobacco products is borne out by e.g., Recital 15.

HTPs are unquestionably a tobacco product category. If a substantial change of circumstance has occurred, the Commission has no discretion and is mandated to disapply the relevant exemption.

There is nothing inconsistent in Article 28(2) as between the obligation on the Commission to monitor market developments in respect of novel tobacco products and to also market developments constituting a substantial change of circumstances. There was no necessary inconsistency between such type of market developments.

Determination of substantial change of circumstances

Article 5(6) makes clear that the volume of sales reported could be either on a weight or stick basis and there was, therefore, nothing improper in the approach taken by the Commission in the Commission Report. The definition of "substantial change of circumstances" itself does not specify the method by which sales volumes are to be assessed. The use of a stick basis to measure sales volume is expressly envisaged and permitted by the terms of the TPD, including by Article 5(6). The implementing decision mandates the provision of data inter alia by stick per product. Data was provided to the Commission in accordance with the requirements of Article 5(6) and the implementing decision.

Reasons for the Reference

Ground 1: Invalidity arguments and alleged breaches of Article 290 TFEU

This Court has held that there are well-founded arguments that the Commission in enacting the delegated directive has impermissibly encroached on the EU legislature's exclusive sphere of legislating contrary to Article 290 TFEU.

In particular, there are well founded arguments as to the invalidity of the delegated directive on the following grounds:

That in defining a new category of tobacco product, being HTPs, and deciding that such category should be denied the benefit of the exemptions in Articles 7(12) and 11(6), the Commission was invalidly making a political choice to the effect that a category of tobacco product which was new on the market, which had not been in existence at the time of the enactment of the TPD and which had not been the subject of separate policy and health assessments by the EU legislature, should nonetheless be prohibited on the basis of the volume of sales. It is at least arguable that this involved a political choice which was only open to the EU legislature and not to the Commission.

That the structure of the TPD is such that the EU legislature would keep novel tobacco products under review in light of scientific and technical developments and that questions of outright prohibition, particularly where products might not be readily categorisable into smokeless tobacco products or tobacco products for smoking, and where such products may not have the same level of tobacco content as existing products, would be addressed by primary legislation once policy choices were made by the legislature as to how best to regulate such new products. To define a new category of product, which straddles both smokeless and smoking tobacco products, for the purposes of immediately prohibiting a flavoured version of such a new product arguably breaches the two limbs of the second subparagraph of Article 290(1) TFEU by purporting to legislate for an essential element and where the scope, content and objective of such a choice was not explicitly defined in the TPD.

The validity arguments presuppose that the Commission would have the delegated power to de-exempt all flavoured novel tobacco products from prohibition if such products met the sales volume conditions of Article 2(28), irrespective of the tobacco content or health impact of such products relative to existing products. This would arguably involve the Commission in the making of political choices which it is not empowered to do.

Ground 2: Alleged fundamental flaw in determination of substantial change of circumstances

This Court has held that there is a well-founded argument as to the validity of the Commission's fulfilment of the task of determining whether there had been a substantial change of circumstances pursuant to Article 2(28). In particular:

The Commission's quantitative sales volume analysis did not compare like with like when such a like for like analysis appears to have been legally and factually open to the Commission. No attempt was made in the Commission's methodology to equalise the metrics as between HTPs and cigarettes (and other tobacco products) as regards tobacco content to ensure that like was compared with like when assessing whether the level of penetration of HTPs in the market was such as to warrant prohibition of flavoured HTPs in furtherance of the health protection objective.

One of the TPD's core objectives is protection of health given the harmful effects of tobacco. Accordingly, tobacco content of tobacco products is a key concern driving the TPD's regulatory measures. An approach which focused on overall tobacco content of products and assessed sales volume on that basis would have arguably been more consistent with these objectives.

There is a reasonable argument that the fact that the Commission may *prima facie* have had the power to approach the analysis by reference to sales volume on a per stick or unit basis did not relieve the Commission of the obligation to ensure that the underlying objectives of the TPD in terms of health protection were best met by another option open to the Commission i.e., that of assessing comparative sales volumes on a tobacco content basis.

Appendix 1

Judgment of the Irish High Court delivered on 15 September 2023